ALLERGY RELIEF- diphenhydramine hcl capsule DOLGENCORP, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DG Health 44-190

Active ingredient (in each banded capsule)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - itchy, watery eyes
 - sneezing
 - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing

Warnings

Do not use

to make a child sleepy

with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

adults and children 12	1 to 2
years and over	capsules
children 6 to under	
12	1 capsule
years	
children under 6	do not uso
years	do not use

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR
 - BROKEN OR IF RED BAND AROUND CAPSULE IS BROKEN OR MISSING
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- see end flap for expiration date and lot number

Inactive ingredients

butylparaben, corn starch, D&C red #28, edible ink, FD&C blue #1, FD&C red #40, gelatin, lactose anhydrous, magnesium stearate, methylparaben, polysorbate 80, propylparaben, silicon dioxide

Questions or comments?

1-888-309-9030

Principal display panel

DGTM Health

Compare to active ingredient of Benadryl® Allergy*

Allergy Relief

Diphenhydramine HCl, 25 mg Antihis tamine

Temporarily Relieves:

- Sneezing Itchy, watery eyes
- Runny nose Itchy nose or throat

Each capsule individually banded for your protection

24 Capsules

25

mg each

100% Satisfaction Guaranteed! (888) 309-9030

DISTRIBUTED BY OLD EAST MAIN CO. 100 MISSION RIDGE GOODLETTSVILLE, TN 37072

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN OR BROKEN OR IF RED BAND AROUND CAPSULE IS BROKEN OR MISSING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl® Allergy.

50844 ORG111719008

50844 800617111980 registered trademark Benadryl® Allergy. Johnson & Johnson Corporation, owner of the . This product is not manufactured or distributed by

Questions or comments? 1-888-309-9030

80, propyiparaben, sincon dioxide magnesium stearate, methylparaben, polysorbate FD&C red #40, gelatin, lactose anhydrous, Inactive ingredients butylparaben, com starch, D&C red ≢28, edible ink, FD&C blue #1,

- see end flap for expiration date and lot number ■ protect from moisture
 - Detween 15°-30°C (59°-86°F) ■ store at 25°C (77°F); excursions permitted
- BBOKEN OB WISSING BROKEN OR IF RED BAND AROUND CAPSULE IS PACKAGE IS OPENED OR BLISTER IS TORN OR ■ TAMPER EVIDENT: DO NOT USE IF OUTER Other information

children under 6 years	asu fon ob
years	100000000000000000000000000000000000000
children 6 to under 12	1 capsule
years and over	
adults and children 12	1 to 2 capsules
do not take more than 6 d	SUDON #5 III SASOD

■ take every 4 to 6 hours Directions

get medical help or contact a Poison Control Center Keep out of reach of children. In case of overdose,

nund racts (confined)

professional before use. If pregnant or breast-feeding, ask a health

- excitability may occur, especially in children operating machinery
- nae cantion when driving a motor vehicle or drowsiness ■ avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase ■ marked drowsiness may occur

When using this product

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prostate gland

- difficulty in unination due to enlargement of the ■ diaucoma chronic bronchitis a breathing problem such as emphysema or Ask a doctor before use if you have
 - diphenhydramine, even one used on skin with any other product containing ■ to make a child sleepy Do not use
 - common cold: I runny nose I sneezing temporarily relieves these symptoms due to the ■ itching of the nose or throat Buizaaus ■ ■ ідсілу, матегу еуез a runny nose other upper respiratory allergies:
- temporarily relieves these symptoms due to hay fever or

Warnings

Diphenhydramine HCI 25 mg Antihistamine

(əınsdeo pəpueq yoeə uı) Purpose Active ingredient

PRODUCT INFORMATION KEEP OUTER PACKAGE FOR COMPLETE

Drug Facts

Allergy Relief

DG health

Compare to active ingredient of Benadryl® Allergy'

Allergy Relief

Diphenhydramine HCl, 25 mg **Antihistamine**

Temporarily Relieves:

- Sneezing
- Itchy, watery eyes
- Runny nose
- Itchy nose or throat

Each capsule individually banded for your protection



TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN OR BROKEN OR IF RED BAND AROUND CAPSULE IS BROKEN OR MISSING

print/No varnish Lot & Exp date

Allergy Relie

mg each



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DG Health 44-190

ALLERGY RELIEF

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-191
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 28 (UNII: 767IP0 Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

Product Characteristics				
Color	PINK, WHITE	Score	no score	
Shape	CAPSULE	Size	14mm	
Flavor		Imprint Code	44;107	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:55910-191-08	2 in 1	CARTON	07/30/2020	
1		12 in	1 BLISTER PACK; Type 0: Not a Combination Product		
_	л. Л т. (r	- 4°		
1	Marketing Inf	orn	nation		
	Marketing Catego	ory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	0 0				
О	TC MONOGRAPH FI	NAL	part341	07/30/2020	

Labeler - DOLGENCORP, LLC (068331990)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(55910-191), PACK(55910-191)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55910-191)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(55910-191)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55910-191)

Revised: 6/2020 DOLGENCORP, LLC